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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,173	08/31/2001	Rachel Meyers	381552003500	3164

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Intellectual Property Group
MILLENNIUM PHARMACEUTICALS, INC.
75 Sidney Street
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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/945,173	MEYERS, RACHEL	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6 and 25-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6 and 25-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 4/20/04.

Election/Restrictions

Applicant's election of Group I (claims 1-3, 6) in the reply filed on 4/20/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 4, 5 and 7-24 have been cancelled. Claims 1-3, 6 and 25-42 are currently pending and are examined herein.

Specification

The disclosure is objected to because of the following informalities: the specification has indicated that a plasmid has been deposited to ATCC (e.g., see p. 2, line 30 of the specification). However, the specification has not indicated the ATCC deposit number. Therefore, the specification is objected to.

Additionally, The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. For example of an embedded hyperlink, see page 12, line 24 of the specification. It is noted that the specification is replete with embedded hyperlinks and all disclosed hyperlinks require correction.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 6 and 25-42 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The instant claims are drawn to an isolated nucleic acid encoding a G-protein coupled receptor (GPCR), as well as related nucleic acids including allelic variants, fragments, etc., as well as a host cell comprising the isolated nucleic acid(s) and methods for producing the polypeptide encoded by the nucleic acid(s).

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a well-established utility exists for the claimed invention. The specification as filed does not disclose or provide any evidence that points to a property of the claimed nucleic acids such that another non-asserted utiliy would be well-established. Additionally, there is no art of record that discloses or provides any evidence that points to a property of the claimed nucleic acids such that another non-asserted utility would be well-established.

The next issue is are any credible utilities cited in the specification for use of these nucleic acids. Cited utilities identified by the examiner include the detection of the nucleic acid itself, screening assays to identify molecules that bind and regulate the polypeptide encoded by the nucleic acids, methods for producing the polypeptide(s) encoded by the nucleic acids, as well as therapeutic treatments using the nucleic acids. These utilities are credible.

The final issue is whether substantial and specific utilities are disclosed in the specification. Here, no substantial utilities which are specific to the nucleic acids encoding the 47324 GPCR are identified. As noted in the utility guidelines, methods of treating unspecified diseases, basic research on a product to identify properties, intermediate products which themselves lack substantial utility are all insubstantial utilities. No substantial utility is identified for the specific 47324 GPCR nucleic acid of the specification, with only speculative utilities that lack any basis provided. Further, none of the recited utilities in the specification are specific to the 47324 GPCR nucleic acid. None rely on any unique feature of this GPCR nucleic acid. That is, there is no substantial utility specific for the claimed nucleic acid because the asserted utilities are utilities which would be applicable to any GPCR, and there are no asserted utilities specific for the 47324 GPCR nucleic acids.

Finally, with regard to the utility analysis, the current situation directly tracks Examples 4 and 12 of the utility guidelines, where a protein of entirely unknown function was characterized as lacking utility. In particular, example 12 states that a receptor does not have utility since no "real world" use is identified, just as in the current situation. Further experimentation is necessary to attribute a utility to the claimed nucleic acid or to the protein which the nucleic acid encodes. (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.) It is also pointed out that the instant nucleic acid encoding a receptor differs from the receptor of Example 12 because in the instant case, the ligand for the 47324 GPCR has not been identified, while the receptor of Example 12 was identified by its ligand which binds to the receptor.

Furthermore, the specification asserts that the claimed nucleic acids can be used to treat disease, however, neither the specification nor the art or record disclose any disease or condition associated with 473245GPCR, the asserted utility in this case is essentially a method of treating an unspecified, undisclosed disease or condition, which does not define a "real world" context of

use. Treating an unspecified, undisclosed disease or condition clearly would require carrying out further experimentation to identify or reasonably confirm a "real world" context of use. *See Brenner v. Manson,* 383 U.S. 519, 535-36, 148 USPQ 689,696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and stated, in context of the utility requirement that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful completion.")

Claims 1-3, 6 and 35-42 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 6 and 28, 33, 38 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to nucleic acids that encode the 47324GPCR and include allelic variants and fragments, etc. Therefore, the claims encompass nucleic acids which are different from those explicitly described in the specification and for which there is an insufficient written description provided.

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (See MPEP 2100-164)

In the instant case, the claims encompass allelic variants, fragments and other variants of the nucleic acid encoding the 47324-GPCR. As such, the claims are drawn to a genus of molecules which encompass thousands and possibly millions of different nucleic acids considering every possible allelic variant, fragment or variant of the disclosed nucleic acid. Applicants have not identified, however, any unique characteristics that are common to all members of the genus wherein the unique characteristics confer a particular function to all molecules possessing that characteristic. That is, the specification has not disclosed any structure-function relationship such that the structure responsible for the desired characteristic

has been identified. Therefore, the applicant has not adequately described the genus of molecules encompassed by the claims.

Additionally, claims 1, 3, 6 and 28, 33, 38 and 40 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement—in view of the written description rejection above. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As mentioned above, the claims encompass sequence for which there is insufficient written description provided in the specification, and includes allelic variants, fragments, and other variants of disclosed sequences. Without a sufficient description of a representative number of species encompassed by the claims, one of skill in the art would not know how to make or use the claimed invention without performing an undue amount of additional experimentation.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-8656. The examiner can normally be reached on Mon-Fri (9-6), with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0756. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
Art Unit 1635

DAVE T. NGUYEN
PRIMARY EXAMINER